

Single Center, Placebo Controlled Clinical Study in Desensitization vs Tolerance Induction in

Peanut Allergy Subjects

Statistical Analysis Plan

NCT02103270

Jan 1st 2017

Statistical analysis

Using a binomial test of proportions with two-sided alpha level 0.05, the subject sample sizes of 60 in the peanut-0 and 25 in the placebo arms yielded 90% power to detect a difference in the success rates, assuming rates of success in the peanut-0 arm between 0.35 and 0.05.

We designed our study and analysis plan before participant enrollment as specified in the protocol. Analyses not specified in the protocol are stated throughout the methods and are considered post-hoc. The primary efficacy analysis compared the peanut-0 and placebo arms using Fisher's exact test.¹⁰ The primary analysis relied on the ITT group and included all subjects randomized to the peanut-0 or placebo arm. Using our endpoint definition (passing the DBPCFC at both 104 and 117 weeks) randomized participants who dropped out of the study were included in the analysis as failures. If any relevant covariates were imbalanced between peanut-0 and placebo, a secondary analysis evaluating the primary endpoint was performed using a multivariable logistic regression model controlling for those variables.

The Supplementary Appendix and study protocol contain more detailed information about the statistical analysis plan. Tests for the primary and secondary analyses were two-sided and conducted at the 0.05 level of significance. All analyses were conducted using R software v3.5.0¹⁰.